DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	7/16/2019-7/19/2019
	FEI NUMBER 3002159099

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lucas J. Bayne, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
M Drug, LLC dba Northern Light Pharmacy	210 State St
CITY, STATE, ZIP CODE, COUNTRY Bangor, ME 04401-5411	TYPE ESTABLISHMENT INSPECTED Producer of Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically:

You produce hazardous drugs in your non-dedicated compounding facility including Tacrolimus (cytotoxic) without providing adequate containment, segregation, cleaning of work surfaces, and cleaning of non-dedicated drug product contact utensils to prevent cross contamination with other hazardous and non-hazardous drug products.

The following deficiencies were observed in your compounding facility and production practices:

A. There is no designed control of airflow or other engineered containment of hazardous compounds processed in the open on the compounding bench. Process steps (b) (4) (b) (4)

B. Clean non-dedicated compounding equipment including (b) (4), and (b) (4) are stored exposed in racks and shelving adjacent to the compounding bench.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator	X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 08-20-2019 07:42:46	8/20/2019

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C. Non-dedicated utensils are not cleaned by methods and cleaning agents shown to adequately remove drug residues to prevent cross contamination during subsequent use on other drug products.

D. Compounding room work surfaces are not cleaned by methods and cleaning agents shown to remove or de-activate hazardous drug compound residues.

E. There is no designed control of airflow direction or pressure differential between the compounding room and adjacent uncontrolled areas to contain hazardous drug substances.

For example: On 07/16/2019, I observed compounding of Prograf (Tacrolimus) 1 mg/ml oral liquid, (b) (4) , (b) (6) under the conditions described above.

OBSERVATION 2

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically:

Your compounding facility is not designed and operated to provide adequate control of microorganisms and environmental particulates to prevent objectionable contamination of non-sterile compounded drug products. The following deficiencies in your compounding facility, practices, and equipment were observed:

There is no designed control of airflow direction, pressure differential, and personnel and equipment movement between the compounding room and adjacent uncontrolled areas to exclude airborne and transported foreign particulates and microorganisms that may contaminate drug products. Furthermore:

a. A window mounted air conditioner is operated in the compounding room above and adjacent

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to the compounding bench. The air conditioner was observed to have visible particulate residues in the vents. There were gaps with light visible between the air conditioner and window frame. There is no pre-filtration of intake air to the air conditioner unit.

b. Personnel are not required to don hair covers during compounding operations.

c. A shelf used to store clean equipment was observed to be chipped to bare pressed wood making it challenging to clean.

d. Some product contact utensils including spatulas were observed with wood handles making them challenging to clean.

OBSERVATION 3

Your Firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically:

A. You do not have data to show that your electronic balance, used to weigh drug components including active pharmaceutical ingredients (API) for formulation of compounded drug products, can deliver accurate and repeatable results ensuring that the correct amounts of drug components are

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added to the drug product. Your electronic balance ((b) (4) (b) (4) used to weigh drug components including APIs for formulation of drug products was not calibrated. Your last service record for the balance from 2009 indicates that a calibration check passed. Furthermore:

a. You do not have specifications for the minimum and maximum capacity of the balance and you have not established the acceptable user range.
b. You do not routinely perform and document balance calibration checks.

B. I observed that the compounding Pharmacy Technician did not use a measuring device to ensure accurate addition of the excipient (b) (4) of several (b) (4) drug products. The Pharmacy Technician performed (b) (4) provided (b) (4) . For example: On 07/16/2019, I observed that the (b) (4) for Prograf (Tacrolimus) 1 mg/ml oral liquid, (b) (4) (b) (6) was performed within the drug (b) (4) Your formulation reference, (b) (4) (b) (4)

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